

Inventor(s): Biaoyang Lin  
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### **REMARKS**

Prior to the present amendment, claims 24 to 32 and 34 to 38 were pending, with claims 27 to 32 withdrawn from examination as allegedly directed to a non-elected invention. Claims 24 and 27 to 38 have been canceled herein, and new claim 72 has been added. Thus, claims 25, 26 and 72 are currently pending.

#### **Regarding the claim amendments**

Claim 25 has been amended to independent form, including all the limitations of its base claim. The amendment to claim 25 does not add new matter.

Claim 38 has been canceled in favor of new claim 72, which is identical to canceled claim 38. Claim 38 was canceled in view of the fact that claims 1 to 71 were present in the patent application as originally filed. Claim 72 does not add new matter.

As set forth above, the amendments and new claim are supported by the specification as originally filed and do not add new matter. Applicant therefore respectfully requests entry of the amendments and new claim.

#### **The objection to claim 25**

The Examiner objects to claim 25 for being dependent upon a rejected base claim. In view of the amendment of claim 25 to independent form, Applicant respectfully requests that the objection to claim 25 be withdrawn.

Rejections Under 35 U.S.C. § 112

**Written Description Rejection**

The rejection of claims 24, 26 and 34 to 37 under 35 U.S.C. § 112, first paragraph, for allegedly lacking sufficient written description, is respectfully traversed.

Regarding claims 24 and 34 to 37

Applicant maintains, for the reasons of record, that the specification provides written description sufficient to reasonably convey to one skilled in the art that Applicant had possession of the ARP3 polypeptides of claims 24 and 34 to 37 at the time the application was filed. The specification discloses, for example, isolation of the human ARP3 cDNA in Example I. In addition, the specification discloses that other ARP3 polypeptides can have 45% or more amino acid sequence identity to SEQ ID NO:5 (page 24, lines 27-30). Further written description for additional ARP3 polypeptides is provided in the specification, which teaches that an ARP3 polypeptide can be, for example, a species homolog of human ARP3 such as a mammalian or non-mammalian homolog of human ARP3. Thus, a variety of ARP3 polypeptides are defined by reference to the human ARP3 sequence (SEQ ID NO: 5) and the recitation of at least 45% amino acid identity to the specified sequence. By teaching species homologs and polypeptides having at least 45% amino acid identity with SEQ ID NO: 5, the specification describes the structural characteristics of the genus of claimed ARP3 polypeptides. In view of the above, Applicant maintains that it is clear to the skilled person that the inventor had possession of the claimed invention at the time the application was filed.

While Applicant maintains that the specification provides sufficient written description for the subject matter of claims 24 and 34 to 37, these claims have been canceled herein in order to further prosecution of the subject application. Applicant notes that claims 24 and 34 to 37 have been canceled without prejudice to Applicant pursuing the subject matter of

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these claims in a related application claiming the benefit of priority of the subject application. In view of the above remarks and amendments, Applicant requests that the Examiner remove the rejection of claims 24 and 34 to 37 as allegedly lacking written description.

Regarding claim 26

In rejecting claim 26 for allegedly lacking written description, the prior Office Action asserts that the claim encompasses unrelated sequences that share the recited number of contiguous amino acids with a portion of ARP3. The Regents of the University of California v Eli Lilly is cited as allegedly supporting the written description rejection. In particular, the Office Action cites Lilly as stating in part that “An adequate written description of a DNA... ‘requires a precise definition, such as by structure, formula, chemical name, or physical properties,’ not a mere wish or plan for obtaining the claimed chemical invention.”

Applicant further maintains that the specification provides sufficient written description for claim 26, directed to an isolated ARP3 polypeptide fragment containing at least ten contiguous amino acids of SEQ ID NO: 5. In particular, adequate written description is provided by the description of a precise structural definition of the claimed ARP3 polypeptide fragments. As set forth in the specification, an ARP3 polypeptide fragment includes an exact stretch of at least ten amino acids of the full-length human ARP3 sequence (SEQ ID NO: 5), shown in Figure 3. In this regard, the specification discloses an ARP3 polypeptide fragment which includes at least eight contiguous amino acids of SEQ ID NO: 5, and further discloses that a polypeptide fragment of the invention also can have, for example, 9, 10, 11, 12, 13, 14, 15, 18, 20, 25, 30, 35, 40, 45 or more contiguous amino acids of the amino acid sequence shown as SEQ ID NO: 5 in Figure 3 (page 23, lines 2-5; page 23, line 30, to page 24, line 8). In regard to polypeptide fragments having at least 8 contiguous amino acids, the specification further discloses exemplary polypeptide fragments having, for example, amino acids 1 to 8, 2 to 9, or 3 to 10, of SEQ ID NO: 5 and other antigenic polypeptide fragments capable of eliciting an

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immune response and thereby generating an antibody selective for an ARP3 polypeptide of the invention (page 23, lines 24-30). Polypeptide fragments including ARP3 polypeptide fragments useful for generating a selective antibody also are disclosed in the specification, for example, at page 30, lines 1-25. In sum, the specification clearly describes ARP3 polypeptide fragments, which contain a portion of the human ARP3 amino acid sequence SEQ ID NO: 5. Instead of a "mere wish or plan," it is clear to the skilled person that Applicant was in possession of the claimed invention, including ARP3 polypeptide fragments having residues 1 to 10, 2 to 11, 3 to 12, 4 to 13, etc. of SEQ ID NO: 5.

In view of the above, the specification clearly provides sufficient written description for the ARP3 polypeptide fragment of claim 26. Accordingly, Applicant respectfully requests that the Examiner remove the written description rejection of claim 26.

**Enablement rejection**

The rejection of claims 24, 26 and 34 to 37 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement, is respectfully traversed.

**Regarding claims 24 and 34 to 37**

Claim 24 is drawn to an ARP3 polypeptide that contains an amino acid sequence having at least 45% amino acid identity with residues 1 to 537 of SEQ ID NO:5, and claims 34 to 37 are drawn to ARP3 polypeptides having, respectively, at least 65%, 75%, 85% or 95% amino acid identity with SEQ ID NO: 5. The Office Action emphasizes that such claims include “variants” of SEQ ID NO:5 which may not have the biological activity of SEQ ID NO: 5.

Applicant maintains for the reasons of record that the specification enables the full scope of the ARP3 polypeptides of claims 24 and 34 to 37. Specifically, in view of the guidance provided in the specification, only routine work would have been required to make and use the claimed ARP3 polypeptides, for example, as antigens for preparation of anti-ARP3 monoclonal antibodies or antisera. The Examiner has previously acknowledged that one skilled in the art would have been able to prepare a human ARP3 polypeptide having the amino acid sequence of SEQ ID NO:5, for example, by routine recombinant methods using the encoding nucleic acid sequence SEQ ID NO:4 (page 14, lines 11-20; page 30, lines 1-4). Applicant maintains that one skilled in the art similarly would have been able to routinely prepare another ARP3 polypeptide encompassed by claim 24 using the guidance provided in the specification. As an example, one skilled in the art would have been able to use recombinant techniques to prepare an ARP3 polypeptide having one or more amino acid substitutions, deletions or insertions as compared to SEQ ID NO:5 (page 24, line 31). Thus, in view of the guidance

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provided in the specification, only standard recombinant techniques would have been required to isolate or prepare an ARP3 polypeptide of claims 24 or 34 to 37.

One skilled in the art also would have known how to use any of the claimed ARP3 polypeptides. Specifically, one skilled in the art would have appreciated that well known techniques for preparing polyclonal or monoclonal antibodies can be used with any ARP3 polypeptide of the invention (page 29, lines 8-12). In sum, in view of routine recombinant techniques and well-established techniques for preparing monoclonal and polyclonal antibodies, undue experimentation would not have been required to make and use the ARP3 polypeptides of claims 24 and 34 to 37. Applicant therefore respectfully requests that the Examiner remove the rejection of claims 24 and 34 to 37 under 35 U.S.C. § 112, first paragraph.

As discussed above, claims 24 and 34 to 37 have been canceled herein without prejudice to Applicant pursuing the subject matter of these claims in a related application claiming the benefit of priority of the subject application. In view of the above remarks and amendments, Applicant further requests that the Examiner remove the enablement rejection of claims 24 and 34 to 37.

Regarding claim 26

One of skill in the art also would have been able to practice the full scope of claim 26, directed to an ARP3 polypeptide fragment containing at least ten contiguous amino acids of SEQ ID NO:5, without undue experimentation. The claimed polypeptide fragment contains exactly the sequence of a portion of the full-length ARP3 sequence (SEQ ID NO: 5), the portion having at least ten contiguous amino acids. Thus, claim 26 does not encompass "variants" of SEQ ID NO:5 but rather is directed to sub-parts of the full-length native human sequence. All that would have been required for one skilled in the art to make and use the invention would have been to chemically synthesize a stretch of at least ten contiguous amino acids of SEQ ID NO:5, using the sequence of SEQ ID NO:5 provided in Figure 3, and to use such a fragment as an immunogen using routine techniques, for example, as set forth in the specification at page 29,

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lines 8-12, and page 30, lines 1-25. In view of the guidance in the specification, only routine laboratory techniques, and not undue experimentation, would have been required to practice the full scope of claim 26.

In view of the above remarks, Applicant respectfully requests that the Examiner reconsider and remove the rejection of claim 26 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement.

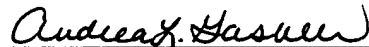
### CONCLUSION

In light of the amendments and remarks herein, Applicant submits that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned agent if there are any questions relating to this patent application.

Respectfully submitted,

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Date



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